Stability Testing in Pharmaceutical Development and Manufacturing - an update for the 21st Century
18 & 19 May 2017
London UK

The course content will provide a comprehensive update on current trends which offer substantial potential savings in time and resources in a traditionally costly and complex testing area. Previous participants say that as a result of the course they have been able to significantly reduce testing in some areas, and identified deficiencies in other areas.

The course will cover:

The impact of the lifecycle approach on product development:

- The implications of implementation of ICH Q7, Q8, Q9, Q10 and Q11 for stability testing
- Changes to European GMP guidance with impact on stability testing including Annexe updates affecting product development, outsourcing and application of Quality Risk Management (QRM)
- Product Quality Reviews, statistics, and the interpretation of stability data

Recent scientific developments with implications for stability, with a particular focus on cost reduction, shortening of development timelines, and improvements on existing interpretation systems.

- ASAP - short term high stress testing to get accurate predictions of shelf life with a high degree of confidence – Freethink Technologies' ASAPprime®
- Low level impurities and their impact on product stability
- Manipulation of tablet internal pH to improve product stability

Speaker:

Dr Michael Gamlen is Managing Director of Pharmaceutical Development Services Ltd, a pharmaceutical consultancy based in Nottingham (UK). Dr Gamlen has over 30 years experience of tablet development. Awarded a First Class Honours degree in Pharmacy, specialising in Pharmaceutical Engineering, he studied for a PhD at Nottingham University. He was Head of Tablet Development at the The Wellcome Foundation for 15 years, and worked as an outsourcing manager before starting his consultancy business in 2000.

Dr Gamlen specialises in managing product development, formulation, tablet and process development studies. He has been teaching professional tabletting courses for many years and his courses are highly rated, exceeding the expectation of the participants in many cases.

Michael continually updates the content of his courses with the latest guidance and extracts of up-to-the minute scientific papers.

He provides a substantial body of relevant literature to all course participants as well as copies of all notes and guidance used and a workbook. He is a highly respected presenter.

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Who will benefit:

The course is designed for people working in:

- Analytical and Product Development
- Analytical Chemistry
- Stability Testing
- Formulation Development
- Regulatory Affairs
- Pharmaceutical & Biopharmaceutical Production
- Quality Control and Quality Assurance
- Technical Operations

Course Programme

Day 1

The course will commence at 8.30 with registration and coffee, course proper will commence at 9.00 and finish at 5.00pm each day

Morning

Introductions

- Quality by Design and the ICH updates QQ7, Q8, Q9, Q10 and Q11 - implications for stability testing

Afternoon

- Changes to EU GMP guidance with implications for stability - Chapter 1 and Annexes
- Product Quality Review and the interpretation of stability data
- Delegate workshop - reviewing delegate-presented problems

DAY 2

Morning

- Low level impurities and their impact on drug product stability.
- ASAP - using short term, high stress testing to get accurate predictions of drug substance and drug product shelf life with high confidence using ASAPprime® software
- Bracketing and matrixing and accurate data interpretation, using the "Stability" software package from Arlenda

Afternoon

- Manipulation of tablet internal pH to improve product stability
- In Silico prediction of drug degradation pathways using the Zeneth software systems
- Action Planning and Final Q&A. **Delegates are encouraged to send data for analysis prior to the course**

Additional Resources

Online access to comprehensive publications including all relevant guidance will be provided as well as colour copies of all presentations and case studies .

COMMENTS FROM PREVIOUS ATTENDEES

"Very good course, would recommend PharmaTraining"
"Very interesting and interactive"
"Good content and delivery

Venue

Hilton London Euston
17 - 18 UPPER WOBURN PLACE, LONDON, WC1H 0HT, UK
Close to Kings Cross/St Pancras and Euston Stations

Website: www.doubletree3.hilton.com

Course fee includes all course materials, refreshments and lunch, accommodation is not included.

Accommodation and travel directions are available on our website

For 5 or more staff requiring training it may be beneficial to run a course in-house.

The benefits of running a course in-house:

- savings on delegate fees
- Save on travel or accommodation costs
- Customised content to meet your requirements
- Big print savings on course material - especially with larger groups
- Courses arranged for large groups up to 24 staff
- Tutorials available for small groups of 2 or 3 staff
- Meet course speakers in advance to discuss design and content

Contact **Judy Callanan at any time to discuss** Ph: ++44 20 7193 7703
Email: judy@pharma-training-courses.com

COURSE PROGRAMME 2017

Hands-on Tablet Development including the principles of pre-formulation, formulation and process development
22, 23 & 24 March 2017 Croydon Greater London

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Pharmaceutical Dissolution Testing - a 2 day course
22 & 23 May London

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Development of Stability-Indicating HPLC Methods
21 June London

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HPLC Analytical Method Development and Validation
22 & 23 June London, 20 & 21 November London

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Pharmaceutical Packaging – an introductory course
26 June London

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Pharmacokinetics in Drug Development - an integrated approach
November London

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GMP Auditor Training for Quality Systems
November London

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Keep up to date with industry requirements

REGISTRATION DETAILS

Stability Testing in Pharmaceutical Development and Manufacturing:

18 & 19 May 2017, London UK

Early-bird fee: 2 day course £1080.00 (+ VAT £216.00 if applicable, see notes on VAT) For registering and paying before **17 March 2017**

Full Fee: 2 day course £1200.00 (+ VAT £240.00 if applicable, see VAT NOTES)

Academic rates are available, please enquire: info@pharma-training-courses.com

VAT NOTES:

UK: Under UK law all UK-based applications are subject to VAT at the prevailing rate however most UK VAT registered companies/organisations can reclaim this tax.

EU: With effect from 1 January 2011 applications from delegates whose companies are based in EU countries will not be subject to VAT **PROVIDED THAT** valid VAT ID details are provided at the time of booking, otherwise VAT will be charged.

OTHER: With effect from 1 January 2011 applications from delegates whose companies are based outside of the UK/EU will be outside the scope of VAT, ie no VAT is charged or payable.

Methods of Payment available:

Cheque (**Please make payable to "PharmaCourses Ltd")**

Bank transfer

Credit/Debit Card (Paying by Credit Card please register online)

Registration is available online:

www.pharma-training-courses.com

Data Protection

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PharmaCourses will not be responsible for any airfare, accommodation or other travel costs incurred.**Delegate fees -** Fees for this programme are shown overleaf.
Delegate fees are inclusive of course documentation, refreshments and lunch.
Payment of the registration fee must be paid within 14 days of commencement of the course. Upon receipt of payment, a proof of payment will be sent to you.
Cancellation Policy - Full refunds less a handling fee of £100 will be made for cancellations received in writing within 28 days of the commencement of the course. Refunds of 50% will be made for cancellations received in writing between 28 and 7 days prior to the commencement of the course. Regrettably no refunds will be made after 7 days prior to commencement of the course. Substitutions can be made at any time.

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